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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/689,483	10/12/2000	Kevin H. Storm	P32685	9497
20462	7590 02/21/2003			
SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539			EXAMINER	
			BENNETT, RACHEL M	
KING OF PRUSSIA, PA 19406-0939			ART UNIT	PAPER NUMBER
			1615	
			DATE MAILED: 02/21/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

•		Application No.	Applicant(s)			
Office Action Summary		09/689,483	STORM ET AL.			
		Examiner	Art Unit			
		Rachel M. Bennett	1615			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHO THE M Extensi after SI - If the pe - If NO pe - Failure - Any rep	PRIENED STATUTORY PERIOD FOR REPLY AILING DATE OF THIS COMMUNICATION. ions of time may be available under the provisions of 37 CFR 1.13 IX (6) MONTHS from the mailing date of this communication. eriod for reply specified above is less than thirty (30) days, a reply seriod for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, ply received by the Office later than three months after the mailing patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be y within the statutory minimum of thirty (30) vill apply and will expire SIX (6) MONTHS fr , cause the application to become ABANDC	e timely filed days will be considered timely. rom the mailing date of this communication. DNED (35 U.S.C. § 133).			
	Responsive to communication(s) filed on 29 N	November 2002				
, —		is action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims						
4)⊠ Claim(s) 13,18 and 69-205 is/are pending in the application.						
4:	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) 🗌 C	5) Claim(s) is/are allowed.					
6)⊠ C	6)⊠ Claim(s) <u>13 and 70-205</u> is/are rejected.					
7) Claim(s) 18, 69 is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12)☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s	;)					
2) Notice of	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ition Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u>	5) Notice of Inform	nary (PTO-413) Paper No(s) al Patent Application (PTO-152)			
S. Patent and Trade PTO-326 (Rev.		tion Summary	Part of Paper No. 13			

Application/Control Number: 09/689,483

Art Unit: 1615

DETAILED ACTION

The examiner acknowledges receipt of Amendment B filed 11/29/02 and Supplemental IDS filed 9/19/02.

Specification

Claim Objections

1. Claims 18 and 69 are objected to because of the following informalities: Claim 18 depends from claims 1, which was cancelled February 11, 2002. Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 13, 70-205 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants do not clearly define the limitations of claims 204 and 205. It is not clear to the examiner if the limitation of "based on blood sampling at half hourly intervals for the first two hours and thereafter at hourly intervals (at the start of a light meal and after an overnight fast)" requires the blood sampling to be taken at the start of a light meal an after an overnight fast. It is suggested Applicants delete the parentheses or the phrase "(at the start of a light meal and after an overnight fast)".
- 4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the

Application/Control Number: 09/689,483

Art Unit: 1615

explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 13, 72-77, 97-102, 109-130, 195-196, 199, 201-203, recites "amoxycillin free acid equivalent" and "clavulanic acid equivalent", and the claim also recites "amoxycillin" and "potassium clavulanate". Clarification is requested.

Response to Arguments

5. Applicant's arguments with respect to claims 13 and 18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Application/Control Number: 09/689,483

Art Unit: 1615

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett February 19, 2003

Collamudi S. Kishore, PhD Primery Examiner Group 1600